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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/806,965	03/22/2004	Alain Rambach	15675P368D	2331

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BLAKELY SOKOLOFF TAYLOR & ZAFMAN  
12400 WILSHIRE BOULEVARD  
SEVENTH FLOOR  
LOS ANGELES, CA 90025-1030

EXAMINER

MARX, IRENE

ART UNIT PAPER NUMBER

1651

DATE MAILED: 11/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/806,965	<b>Applicant(s)</b> RAMBACH ET AL.	
	<b>Examiner</b> Irene Marx	<b>Art Unit</b> 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE \_\_\_\_\_ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 16 October 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) 1-6 and 8 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 7 and 9-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

The application should be reviewed for errors.

To facilitate processing of papers at the U.S. Patent and Trademark Office, it is recommended that the Application Serial Number be inserted on every page of claims and/or of amendments filed.

Applicant's election without traverse electing to prosecute the invention of Group II, claims 7 and 9-12 on 10/16/06 is acknowledged.

Claims 7 and 9-12 are being considered on the merits. Claims 1-6 and 8 are withdrawn from consideration as directed to a non-elected invention.

#### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7 and 9-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 7 and 9-12 are vague, indefinite and confusing in being incomplete as depending on a non-elected claim.

Claim 7 is vague, indefinite and confusing in the missing a verb prior to "added", such as --is-- to denote an active step in the process. There is lack of agreement between the "detection" requirement in the preamble and the body of the claim. All the claim requires is that the medium "may contain said bacteria cultured under anaerobic conditions" and that "the appearance of a colored precipitate around the colonies (halo) and/or a color of the colonies is visualized". There is no clear indication if "detection" occurs and the nature of "bacteria" detected.

Claim 7 is vague, indefinite and confusing to the extent that it depends on claim 1 in the recitation "indoxyl derivative", since the "derivatives" intended are not defined with any specificity. Are these chemical, physical or biological "derivatives"?

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Claims 9-12 provide for the use of a composition, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 9 is confusing in that the phrase "it being possible for said substrate to be a substrate selected from" is not a positive recitation. Moreover, A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 9 recites the broad recitation of a variety of substrates, and the claim also recites "preferably X-Gal" which is the narrower statement of the range/limitation.

Claims 9-12 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 7 and 11-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Haines *et al.*.

The claims appear to be directed to a method for the detection of bacteria, wherein at least one oxidizing metal complex and at least one substrate containing an indoxyl derivative are used for the detection of bacteria, which may be cultured anaerobically.

Haines *et al.* disclose a method of detection of bacteria wherein simmon's citrate agar is used in conjunction with MUG, and wherein the bacterial colonies are detected.

Regarding the limitation "may contain said bacteria cultured under anaerobic conditions", this is seen as a product by process limitation, which is conditional. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted) (Claim was directed to a Novolac color developer. The process of making the developer was allowed. The difference between the inventive process and the prior art was the addition of metal oxide and carboxylic acid as separate ingredients instead of adding the more expensive pre-reacted metal carboxylate. The product-by-process claim was rejected because the end product, in both the prior art and the allowed process, ends up containing metal carboxylate. The fact that the metal carboxylate is not directly added, but is instead produced in-situ does not change the end product.).

Furthermore, the composition is claimed as a product-by-process. Since the U.S. Patent and Trademark Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make comparisons therewith, a lesser burden of proof is required to make out a case of prima facie anticipation/obviousness for product-by-process claims because of their peculiar nature than when a product is claimed in the conventional manner. MPEP 2113. Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a

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sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the *prima facie* case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. In re Best, 562 F.2d at 1255, 195 USPQ at 433.

Therefore, the claims are anticipated by the reference.

Claims 7 and 9-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haines *et al.* taken with Chevalier *et al.*.

The claims appear to be directed to a method for the detection of bacteria, wherein at least one oxidizing metal complex and at least one substrate containing an indoxyl derivative are used for the detection of bacteria, which may be cultured anaerobically.

Haines *et al.* disclose a method of detection of bacteria wherein simmon's citrate agar is used in conjunction with MUG, and wherein the bacterial colonies are detected. The reference differs from the invention as claimed in that X-gal is not used. However, Chevalier *et al.* disclose a method of detecting bacteria grown anaerobically (page 77, last two lines) using X-gal as the substrate wherein at least one oxidizing metal complex and at least one substrate containing an indoxyl derivative are used for the detection of bacteria.

Accordingly, one of ordinary skill in the art would have had a reasonable expectation of success in detecting anaerobic bacteria by modifying the process of Haines by substituting MUG by X-Gal as a substrate in view of the teachings of Chevalier *et al.* regarding the successful detection of anaerobic bacteria with this indoxyl derivative.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the detecting process as taught by Haines *et al.* by replacing MUG with X-Gal in a process of detecting anaerobic bacteria for the expected benefit of detecting and differentiating a greater variety of pathogenic and deleterious bacteria in food and water, for example, with a more sensitive detection test.

Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

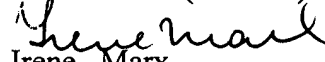
No claim is allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (571) 272-0919. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300 .

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Irene Marx  
Primary Examiner  
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